

PSODEX PSORIASIS CREAM STANDARD THERAPY- coal tar cream
Psodex USA Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Psodex Psoriasis Cream Standard Therapy

Drug Facts

Active ingredient

Coal Tar 0.5%

Purpose

Psoriasis cream

Use

Controls the symptoms of psoriasis

Warnings

For external use only

When using this product

- Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.
- Use caution in exposing skin to sunlight after applying this product. It may increase your tendency to sunburn up to 24 hours after application.

Do not use

- For prolonged periods of time without consulting a doctor.
- In or around the rectum or in the genital area or groin except on the advice of a doctor.
- With other forms of psoriasis therapy such as ultraviolet radiation or prescription drugs unless directed to by a doctor.

Ask a doctor before use if

condition covers a large area of the body

Stop use and ask a doctor if

condition worsens or does not improve after regular use of this product as directed.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply to affected areas one to four times daily or as directed by a doctor.

Other information

Store at controlled room temperature 15°-30°C (59°-86°F)

Inactive ingredients

Allantoin, Aloe Barbadensis Leaf Extract, Borage Seed Oil, Butyrospermum Parkii (Shea) Butter, Caprylic Capric Triglyceride, Caprylyl Glycol, Centella Asiatica Whole Extract, Cetearyl Alcohol, Cetearyl Oliviate, Curcuma Longa Extract, D -Camphor Natural, D-Panthenol, Distilled Water, Ethylhexylglycerin, Frankincense Oil, Fumaria Officina is Extract, Genistein, Glycyrrhiza Glabra (Licorice) Root Extract, Mentha Piperita Leaf Extract, Pumpkin Seed Oil, Rosemary Leaf Oil, Salicylic Acid, Sorbitan Oliviate, Stearic Acid, Tea Tree Leaf Oil, Vegetable Glycerin, Vitamin B3, Vitamin E, Zinc Acetate.

Questions or Comments?

1-844-PSODEXUSA info@psodexusa.com

Package Labeling:



PSODEX PSORIASIS CREAM STANDARD THERAPY

coal tar cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73503-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COAL TAR (UNII: R533ES02EC) (COAL TAR - UNII:R533ES02EC)	COAL TAR	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BORAGE SEED OIL (UNII: F8XAG1755S)	
SHEA BUTTER (UNII: K49155WL9Y)	

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
TURMERIC (UNII: 856YO1Z64F)	
DEXPANTHENOL (UNII: 1O6C93RI7Z)	
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
FRANKINCENSE OIL (UNII: 67ZYA5T02K)	
GENISTEIN (UNII: DH2M523P0H)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
PUMPKIN SEED OIL (UNII: 6E5QR5USSP)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERIN (UNII: PDC6A3C0OX)	
NIACIN (UNII: 2679MF687A)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
ZINC ACETATE (UNII: FM5526K07A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73503-005-01	1 in 1 BOX	03/01/2021	
1		100 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	03/01/2021	

Labeler - Psodex USA Inc. (076051073)

Revised: 1/2021

Psodex USA Inc.